Applicant: Oppmann, et al. Attorney's Docket No.: 16622-005001 / DX01042X

Serial No.: 09/658,699

Filed: September 8, 2000

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<u>REMARKS</u>

It is respectfully requested that this application be reconsidered in view of the above amendments and the following remarks and that all of the claims remaining be allowed.

Amendments in the Specification

The paragraph beginning at page 8, line 42 has been amended by inserting sequence identifiers and source animals of the sequences. Support for these amendments can be found, for example, in U.S. Pat. No. 5,650,492 and the Genbank entries disclosed in the same paragraph, which patent and Genbank entries are incorporated by reference (see, e.g., page 7, lines 28-30).

A substitute sequence listing is submitted in both paper and computer readable form (CRF). SEQ ID NOs:6-36 have been added in this substitute sequence listing. Support for these newly added sequences can be found in U.S. Pat. No. 5,650,492 and the Genbank sequence information for each added sequence. Pursuant to 37 C.F.R. §1.821(f), the undersigned hereby states that the information recorded in the CRF is identical to the written sequence listing contained in the paper copy submitted herewith, and that the submission does not include any new matter.

Pursuant to MPEP § 608.01(p), a declaration by the undersigned is submitted herewith, stating that the amendatory material consists of the same material incorporated by reference in the present application.

Claim Amendments

Claims 63, 69 and 74 have been amended to recite SEQ ID NO:6 or 8, support for which can be found, for example, in the paragraph beginning at page 8, line 42.

Claim 63 has also been amended by deleting "determining the specificity of the antibody raised in step (a) using the IL-B30/p40 complex or fusion protein", as the remaining recitation "confirming that said antibody binds to the IL-B30/p40 complex or fusion protein" is sufficiently clear.

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Claim 69 has been rephrased to recite "detecting if the candidate antibodies or fragments bind the IL-B30 or p40 subunit, and selecting the antibody or fragment that does not bind the IL-B30 or p40 subunit" without changing the scope of the claim.

No new matter has been added by these amendments. The Examiner is hereby requested to enter these amendments.

Applicants submit that all claim amendments presented herein or previously are made solely in the interest of expediting allowance of the claims and should not be interpreted as acquiescence to any rejections or ground of unpatentability. Applicants reserve the right to file at least one continuing application to pursue any subject matter that is canceled or removed from prosecution due to the amendments.

Rejections Under 35 U.S.C. §112, Written Description

The rejection of claims 63-66 under 35 U.S.C. §112, first paragraph, is respectfully traversed for the reasons set forth below.

Specifically, the Office Action states that the claims recite the IL-12 p40 subunit, but there is allegedly no information regarding the sequence of the p40 subunit in the specification. Accordingly, the Office Action takes the position that the specification does not disclose the structure of Il-12 p40, and concludes that Applicants were not in possession of the claimed invention under *Regents of the University of California v. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997).

Applicants submit that the sequence of the IL-12 p40 subunit has been well known to those of skill in the art. For example, the specification teaches numerous references and Genbank sequence information that disclose the sequences of IL-12 p40 from various animals (see, e.g., the paragraph beginning at page 8, line 42). In *Capon v. Eshhar*, 418 F.3d 1349, 1360-1361, 76 U.S.P.Q.2d 1078, 1089 (Fed. Cir. 2005), the Federal Circuit held that 35 U.S.C. §112

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does not impose a *per se* rule requiring recitation in the specification of the nucleotide sequence of claimed DNA, when that sequence is already known in the field. The Federal Circuit also pointed out that established case law, including *Regents v. Lilly*, does not require a re-description of what was already known. *Capon v. Eshhar*, 418 F.3d at 1357, 76 U.S.P.Q.2d at 1086. Since the sequence of IL-12 p40 is known in the art, the previously presented claims satisfy the written description requirement.

Nevertheless, in the interest of expediting prosecution of this application, claim 63 has been amended to identify the IL-12 p40 subunit as having SEQ ID NO:6 or 8. Therefore, this rejection has been obviated.

In view of the above, withdrawal of this rejection is respectfully requested.

Rejections Under 35 U.S.C. §112, Second Paragraph

The rejection of claims 63-66, 69-73 and 79 under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention, is now moot for the reasons set forth below.

The Office Action states that claim 63 is allegedly vague due to the recitation of "using" in the phrase "determining the specificity of the antibody raised in step (a) using the IL-B30/p40 complex or fusion protein." Applicants disagree. However, since this phrase has been deleted from claim 63, this part of the rejection is now moot.

The Office Action also states that claim 69 is allegedly ambiguous and unclear for reciting "contacting" the candidate antibodies or fragments with bind the IL-B30 and p40 subunits. As amended, the claim now recites "detecting if the candidate antibodies or fragments bind the IL-B30 or p40 subunit, and selecting the antibody or fragment that does not bind the IL-B30 or p40 subunit." Thus, this part of the rejection is also moot.

Accordingly, withdrawal of this rejection is respectfully requested.

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Conclusions

For the reasons set forth above, Applicants submit that the claims of this application are patentable. Reconsideration and withdrawal of the Examiner's objections and rejections are hereby requested. Allowance of the claims remaining in this application is earnestly solicited.

In the event that a telephone conversation could expedite the prosecution of this application, the Examiner is requested to call the undersigned at (650) 839-5044.

Enclosed is a \$120 check for the Petition for Extension of Time fee. Please apply any other charges or credits to deposit account 06-1050.

Respectfully submitted,

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Feb. 3, 2006

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